

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

KENNETH DUNHAM and MARTHA
DUNHAM

Plaintiffs,

v.

COVIDIEN LP

Defendant.

Civil Action No.: 1:19-cv-02851

**FIRST AMENDED COMPLAINT AND
JURY DEMAND**

Plaintiffs, Kenneth Dunham and Martha Dunham, by and through their attorneys, Marc J. Bern & Partners LLP, complaining of the Defendant, respectfully allege upon information and belief:

PARTIES

1. Plaintiff, Kenneth Dunham, (“Plaintiff”) is an individual and resident of the State of New York.
2. Plaintiff resides at 13 West 12th Avenue, Gloversville, New York 12078.
3. Defendant, Covidien LP, (“Defendant”), is a Delaware Limited Partnership, headquartered at 15 Hampshire Street, Mansfield, Massachusetts 02048, with an additional place of business located at 480 Washington Blvd, Jersey City, NJ 07310.
4. Defendant derives substantial revenue from sales directed at and occurring within the State of New York, including the ProGrip™ Mesh and Paritex™ Mesh, (“Products”), the subjects of the present action.
5. Defendant is and has been at all times pertinent to this proceeding, engaged in the design and manufacturing of medical technologies used by surgeons to treat a variety of conditions, including, but not limited to, hernia repairs.

6. The Defendant corporation designed, manufactured, packaged, labeled, marketed, sold, and distributed one or more of the hernia mesh products at issue in this lawsuit.

JURISDICTION and VENUE

7. Jurisdiction is proper in this Court pursuant to C.P.L.R. § 302(a)(3) because a substantial part of the events and omissions giving rise to Plaintiff's causes of action occurred in the State of New York. Specifically, Plaintiff is a New York resident, Plaintiff's product was purchased in New York, Plaintiff's product was implanted in New York, and Plaintiff's injury occurred in New York.

8. Further, jurisdiction is proper in this Court pursuant to C.P.L.R. § 302(a)(3), by virtue of the fact that Defendant's products were produced in, sold to, and implanted in individuals in the State of New York, thereby subjecting Defendant to personal jurisdiction in this action. Plaintiff's claim arises from Defendant's presence and transactions in New York. Defendant's activities within New York were purposeful and are substantially related to Plaintiff's injuries, which occurred in New York. Defendant at all times relevant, regularly conducted and solicited, and continue to conduct and solicit, business in the State of New York through its agents, servants and employees, and because Defendant was engaged, and continue to engage, in marketing, distributing, promoting, and/or selling, either directly or indirectly, and/or through third parties or related entities, product, including but not limited to hernia mesh product, in New York. Defendant at all times relevant engage, and continue to engage, in a persistent course of conduct in the State of New York. Defendant derive substantial revenue from goods used or consumed or services rendered in the State of New York. Defendant expect or should reasonably expect its actions and course of conduct to have consequences in the State of New York and derive substantial revenue from interstate and/or international commerce.

9. Covidien Defendant actively sells, markets and promotes its product (ProGrip Mesh™) to physicians and consumers in this state on a regular and consistent basis.

10. Defendant systematically availed themselves of the State of New York by conducting regular and sustained business and engaging in substantial commerce and business activity in New York, including without limitation researching, developing, designing, setting specifications for, licensing, manufacturing, preparing, compounding, assembling, processing, marketing, promoting, distributing, selling, and/or introducing into interstate commerce in the State of New York, either directly or indirectly, its product, including hernia mesh product. Defendant should expect that its acts would have consequences within the United States, specifically, in the State of New York. Plaintiff's claims arise from and relate to Defendants purposeful availment of the State of New York because Defendant's wrongful conduct in researching, developing, designing, setting specifications for, licensing, manufacturing, preparing, compounding, assembling, processing, marketing, promoting, distributing, selling, hernia mesh product, took place, in whole or in part, in the State of New York. Therefore, the claims of this New York Plaintiff relate to and arise from Defendant's explicit contacts and purposeful availment of the State of New York.

11. Venue is proper pursuant to C.P.L.R § 509.

ESTOPPEL FROM PLEADING STATUTES OF LIMITATIONS OR REPOSE

12. Plaintiff incorporates by reference all prior allegations.

13. Plaintiff is within the applicable statute of limitations for his claims because Plaintiff, and his health care professionals, did not discover, and could not reasonably discover, the defects and unreasonably dangerous side effects of Defendant's mesh products.

14. Plaintiff's ignorance of the defective and unreasonably dangerous nature of the ProGrip™ Mesh and Parietex™ Mesh, and the causal connection between the defects and

Plaintiff's injuries and damages, is due in large part to Defendant's acts and omissions in fraudulently concealing information from the public and misrepresenting and/or downplaying the serious threats to public safety its product present.

15. In addition, Defendant is estopped from relying on any statutes of limitation or repose by virtue of unclean hands, acts of fraudulent concealment, affirmative misrepresentations and omissions.

16. Such conduct includes intentional concealment from Plaintiff, promotion to health care professionals, the general public, and the FDA of material information that the ProGrip™ Mesh and Parietex™ Mesh had not been demonstrated to be safe or effective, and carried with it the risks and dangerous defects described herein.

17. Defendant had a duty to disclose the fact that the ProGrip™ Mesh and Parietex™ Mesh were not safe or effective, was defective, unreasonably dangerous, and that being implanted with ProGrip™ Mesh and Parietex™ Mesh as a remedy to a hernia as well as measures of prevention from hernia recurrence carried the above-described risks.

FACTUAL BACKGROUND

I. HERNIAS, HERNIA MESH PRODUCTS AND KNOWN ALTERNATIVES

18. A hernia is a medical condition caused by the penetration of fatty tissue, intestine, or organs through a weakened or compromised location in muscle or connective tissue.

19. The most common types of hernias are: inguinal, hiatal, umbilical, ventral, incisional, and femoral hernias, most occurring near the abdominal wall.

20. Hernias sometimes manifest as visibly observable protrusions or bulges, and can cause the patient pain, discomfort, and decreased mobility.

21. Hernias can be treated surgically, either by laparoscopic or open repair surgical procedures.

22. Hernia repairs are common surgeries, and are performed more than one-million times per year in the U.S. Of all hernia repair surgeries, inguinal hernias account for approximately 80% of all hernia surgeries (an excess of 800,000 performed annually).

23. The surgical mesh used to execute hernia repairs to damaged tissue can be constructed from synthetic or biologic materials and tissue.

24. Synthetic surgical mesh is made of knitted or non-knitted sheets that can be absorbable, non-porous, or a combination of absorbable and nonabsorbent in composition.

25. Surgical mesh can be introduced to the hernia site to strengthen the repair.

26. Hernia mesh made from animal byproduct is usually derived from animal tissue sourced from skin or intestine and is designed to be absorbed into the human body upon use.

27. Non-absorbable mesh, made from synthetic materials, is intended to remain within the body permanently.

28. The most common injuries caused by hernia surgeries using hernia mesh are: pain, infection, adhesion of scar tissue sticking together, blockages that obstruct intestines, internal bleeding, fistula between organs (abnormal organ connection or fusion), seroma or fluid build-up at site, and perforation of other organs.

29. The hernia mesh that is introduced to the body, through this procedure, can cause serious injuries, including migration of the mesh and mesh shrinkage or contraction as well as the aforementioned conditions.

30. Additional defects and known side effects of hernia mesh, as used for reinforcement and strengthening of hernia repairs, include:

- a. Mesh materials, as used, react to human tissues, organs and other body contents adversely.
- b. Mesh materials can harbor or cultivate infections, which can affect surrounding areas, tissues, and organs.

- c. Mesh material abrades bodily tissue and can cause erosion of tissue and organs surrounding the placement of the mesh implant.
- d. Mesh components routinely fail, malfunction or lose efficacy, resulting in serious adverse health implications, often requiring subsequent revision or removal surgery.
- e. Mesh material causes significant injury, extending to perforation of surrounding tissue and/or organs, adhesion to other tissue and/or organs, and nerve damage.
- f. MMesh material is intended to be rounded and reinforced to be safely cut, but when mesh is defective, it can become frayed, sharp, and protruding.
- g. UUnreasonable risk of malfunction, injury and health consequences, such as: severe chronic pain, infection, adhesion, intestinal blockages, migration of mesh, contraction/shrinkage of mesh, and requirement of repeat surgical intervention.

31. In April of 2016, the FDA wrote and published an article on hernia mesh implants:

“Many complications related to hernia repair with surgical mesh that have been reported to the FDA have been associated with recalled mesh product that are no longer on the market. Pain, infection, recurrence, adhesion, obstruction, and perforation are the most common complications associated with recalled mesh.”

32. Safer and more effective alternatives to hernia mesh exist and have existed since the introduction of hernia mesh product into the market. These include the Shouldice Repair, McVay Repair, Bassini Repair, and Desarda Repair.

33. Alternative designs for hernia mesh product and/or procedures existed that were and/or are less dangerous and equally, if not more, effective, including the use of polycarbonate and polystyrene as alternatives.

II. DEFENDANTS PROGRIP™ LAPAROSCOPIC SELF-FIXATING MESH

34. Defendant's ProGrip™ Laparoscopic Self-Fixating Mesh was designed, patented, manufactured, labeled, packaged, marketed, sold, and distributed by Defendants at all relevant times herein.

35. Defendant was responsible for the research, design, development, testing, manufacture, production, marketing, packaging, promotion, distribution, and sale of the Covidien ProGrip™ Laparoscopic Self-Fixating Mesh, as well as providing the warnings and instructions concerning the product.

36. Among the intended purpose for which Covidien designed, manufactured, marketed, and sold the Covidien ProGrip™ Laparoscopic Self-Fixating Mesh, was for the use by surgeons for hernia repair surgeries, the purpose for which the Covidien ProGrip™ Laparoscopic Self-Fixating Mesh, was implanted in Plaintiff, David T. Caparrelli.

37. Defendant's ProGrip™ Laparoscopic Self-Fixating Mesh is designed, intended and utilized for permanent implantation in the human body.

38. Defendant applied for U.S. Food and Drug Administration ("FDA") clearance to market its the ProGrip™ Laparoscopic Self-Fixating Mesh under Section 510(k) of the Medical Device Amendment.

39. Section 510(k) allows for the marketing of medical devices, so long as the medical device or material is deemed substantially equivalent to other legally marketed predicate devices or materials without predicate devices without formal review for the safety or efficacy of the device.

40. Defendant obtained clearance by a 510(k) application, submitted on November 26, 2014, and approved by the FDA on March 13, 2015 as 510(k) No.: K143386.

41. Based on the 510(k)-clearance procedure, Defendant bypassed the requirement to have the Covidien ProGrip™ Laparoscopic Self-Fixating Mesh independently evaluated by the FDA or its experts.

42. In promotional and informational materials about the ProGrip™ Laparoscopic Self-Fixating Mesh on Defendant's website, the ProGrip™ Mesh is described as follows: "increases the security of the laparoscopic inguinal hernia repair," "low post-operative pain and fast recovery," and "preserves cord and nerve structures."

43. The ProGrip™ Mesh is a lightweight, semi-resorbable mesh designed for tack-free (and suture-free) fixation in the body; it is comprised of a monofilament polyester (PET) material, a collagen film, and a resorbable polylactic acid (PLA) gripping system.

44. Polyester is a synthetic fiber derived from coal, air water, and petroleum.

45. Polyester is used chiefly to make synthetic textile fibers commonly found in clothing, home furnishings, and recording tapes.

46. In the ProGrip™ Laparoscopic Self-Fixating Mesh, polyester fibers are constructed into a macroporous design which allows the mesh to be stretched in different directions.

47. Collagen is a protein found in connective tissue all throughout the body.

48. These materials, polyester and collagen, respectively, are designed to work in concert to reinforce soft tissue and minimize tissue attachment to the mesh device in case of direct contact with internal organs.

49. However, the collagen film fails to mitigate the body's adverse reaction to the non-absorbable polyester mesh.

50. Polyester is prone to tearing, ripping, and/or fraying.

51. Once the polyester fibers unravel, they become detached from the mesh and migrate to other regions of the body.

52. These polyester fibers, once they become imbedded in different regions of the body, create an inflammatory response.

53. The collagen film which was designed to make the polyester textile more tolerable to the body is extremely delicate.

54. Once the collagen barrier dissolves, internal organs are left unprotected from the dangers associated with the synthetic polyester textile.

55. Once the collagen barrier dissolves, it leaves the internal organs unprotected and increases the chances of adhesions, inflammatory response to the polyester, and formation of devastating scar tissue.

56. In addition to the polyester fibers unraveling, the mesh can also cause nerve damage.

57. Nerves grow into the macro pores of the polyester textile after implant.

58. Polyester mesh contracts overtime, causing tension to increase where it is secured.

59. The stretching of the nerves causes debilitating pain. Additionally, this pain caused from the stretching of the nerves is essentially unable to be treated.

60. With this in mind, Covidien attached thousands of “micro-grips” to the mesh for a “stronger,” “tension-free” hernia repair.

61. However, micro-grip technology does not prevent the polyester material from contracting and pulling on the tissues and nerves upon which the micro-grips are attached.

62. Several clinical studies indicate self-gripping mesh is not associated with lower rates of chronic and severe post-operative pain or hernia recurrence than is traditional mesh that requires tacks or sutures.

63. The FDA maintains an active compulsory database (“MAUDE Database”) of adverse incidents reported by medical providers regarding pharmaceutical implants and devices.

64. Every year, the FDA receives hundreds of medical device reports (“MDRs”) of suspected device- associated deaths, serious injuries, and malfunctions to contribute to the medical community’s risk-benefit analysis of the use of certain devices.

65. Several MAUDE reports have been published documenting serious incidences of malfunction of Covidien’s Covidien ProGrip™ Laparoscopic Self-Fixating Mesh material.

66. Among the MAUDE reports are documented instances of severe pain, nausea, vomiting, incarcerated hernia recurrence, and complications with attempted removal.

III. DEFENDANTS PRIETEX™ OPTIMIZED COMPOSITE MESH

67. Defendant’s Parietex™ Mesh, was designed, patented, manufactured, labeled, packaged, marketed, sold, and distributed by Defendant at all relevant times herein. Covidien Defendant was responsible for the research, design, development, testing, manufacture, production, marketing, packaging, promotion, distribution, and sale of Parietex™ Mesh, as well as providing the warnings and instructions concerning the product.

68. Among the intended purposes for which Defendant designed, manufactured, marketed, and sold, Parietex™ Mesh was for the use by surgeons for hernia repair surgeries -- the purpose for which the Parietex™ Mesh was implanted in the Plaintiff, Kenneth Dunham.

69. Defendant’s Parietex™ Optimized Composite Mesh is designed, intended, and utilized for permanent implantation in the human body.

70. Defendant represented to Plaintiff and Plaintiff’s physicians that the Parietex™ Optimized Composite Mesh was safe and effective product for hernia repair and permanent implantation in humans.

71. Defendant applied for U.S. Food and Drug Administration (“FDA”) clearance to market its Parietex™ Mesh under Section 510(k) of the Medical Device Amendment.

72. Section 510(k) allows for the marketing of medical devices, so long as the medical device or material is deemed substantially equivalent to other legally marketed predicate devices or materials without predicate devices without formal review for the safety of efficacy of the device.

73. Defendant obtained clearance by a 510(k) application, submitted on March 24, 2011, and approved by the FDA on April 19, 2011 as 510(k) No: K110815.

74. Based on the 510(k)-clearance procedure, Defendant bypassed the requirement to have Parietex™ Mesh independently evaluated by the FDA or its experts.

75. In promotional and information materials about Parietex™ Mesh on the Defendant's website, the Parietex™ Mesh is described as follows: "minimizes visceral attachments with a stronger, more damage-resistant barrier"; "encourages rapid abdominal wall integration with large pore x-stitch textile design"; "easy to use with improved visibility and pre-placed sutures."

76. The Parietex™ Mesh is a two-sided mesh device made up of a three-dimensional multifilament polyester knit textile on one side and an absorbable collagen film barrier on the other side.

77. Polyester is a synthetic fiber derived from coal, air, water, and petroleum.

78. Polyester is used chiefly to make synthetic textile fibers commonly found in clothing, home furnishings, and recording tapes.

79. In the Parietex™ Mesh device, polyester fibers are knit into a x-stitch textile; this design creates macro pores (holes) throughout the mesh and allows the mesh to be stretched in different directions.

80. Collagen is a protein found in connective tissue all throughout the body.

81. These materials, polyester and collagen, respectively, are designed to work in concert to reinforce soft tissue and minimize tissue attachment to the mesh device in case of direct contact with internal organs.

82. However, the collagen film fails to mitigate the body's adverse reaction to the non-absorbable polyester mesh.

83. Once the collagen barrier dissolves, it leaves the internal organs unprotected and increases the chances of adhesions, inflammatory response to the polyester, and formation of devastating scar tissue.

84. Polyester is prone to tearing, ripping, and/or fraying.

85. Once the polyester fibers unravel, they become detached from the mesh and migrate to other regions of the body.

86. These Polyester fibers, once they become imbedded in different regions of the body, create an inflammatory response.

87. In addition to the polyester fibers unraveling, the mesh can also cause nerve damage.

88. Nerves can grow into the pores of the x-stitch textile after implant.

89. Polyester mesh contracts overtime, causing tension to increase where it is secured by tacks or sutures.

90. The stretching of the nerves causes debilitating pain.

91. This pain caused from the stretching of the nerves is essentially unable to be treated.

92. Multifilament polyester hernia mesh product are associated with higher rates of medical complications per patient, including but not limited to: infection, small bowel obstruction, fistula formation, and hernia recurrence.

93. As a result, several clinical studies have recommended against the use of macro-porous polyester mesh for incisional hernia repair.

94. The collagen film which was designed to make the polyester textile more tolerable to the body is extremely delicate.

95. Once the collagen barrier dissolves, internal organs are left unprotected from the dangers associated with the synthetic polyester textile.

96. The FDA maintains an active compulsory database (“MAUDE Database”) of adverse incidents reported by medical providers regarding pharmaceutical implants and devices. Every year, the FDA receives hundreds of medical device reports (“MDRs”) of suspected device-associated deaths, serious injuries, and malfunctions to contribute to the medical community’s risk-benefit analysis of the use of certain devices.

97. Several MAUDE reports have been published documenting serious incidences of malfunction of Covidien Defendant’s Parietex™ Optimized Composite Mesh material.

98. Among the MAUDE reports are documented instances of ineffective collagen films and polyester materials which are prone to unraveling, fraying, and tearing.

99. As a result, patients have experienced hernia recurrence, swelling, severe abdominal pain, bowel perforation, mesh migration, bacterial infection, adhesion, coma, and even death.

IV. PLAINTIFF SPECIFIC FACTS

100. At all times relevant to this action Plaintiff, Kenneth Dunham, was and is a resident of the State of New York, residing at 13 West 12th Avenue, Gloversville, New York 12078.

101. On September 26, 2005 Plaintiff, Kenneth Dunham, underwent an umbilical hernia repair procedure performed by Ronald Marsh, M.D. where a Ventralex Hernia Patch was implanted into Plaintiff.

102. On February 18, 2016 Plaintiff, Kenneth Dunham, underwent a subsequent surgery performed by Ronald Marsh, M.D. to repair an incarcerated incisional hernia and introduce Defendant's ProGrip™ Laparoscopic Self Fixating Mesh to Plaintiffs abdomen to reinforce tissue affected by the hernia.

103. Defendant's ProGrip™ Laparoscopic Self Fixating Mesh was used for Plaintiff Kenneth Dunham's surgery. Specifically, ProGrip™ Laparoscopic Self Fixating Mesh 5x6 cm, LOT No. RPI0273X as positively identified on surgical and operative reports prepared by Marsh, was implanted into Plaintiff.

104. On or about April 1, 2016 Plaintiff underwent a subsequent surgery to excise and close an abdominal wall wound in the location of his hernia repair. The procedure was performed by Ronald Marsh, M.D.

105. On or about August 8, 2017 Plaintiff Kenneth Dunham underwent a recurrent hernia repair performed by Edward Choongho Lee M.D. where Defendant's Parietex™ mesh was implanted into Plaintiff's peritoneal cavity.

106. Specifically, Defendant's Parietex™ 10x10 cm Lot No.: PR83630X was implanted into Plaintiff, Kenneth Dunham.

107. Defendants Parietex™ mesh remains implanted in Plaintiffs abdomen.

108. Plaintiff has experienced and continues to experience stomach pain since the multiple procedures and hernia mesh implants.

109. Plaintiff Kenneth Dunham has experienced and continues to experience abdominal pain, significant bothersome scar tissue, building in his abdomen, and recurrent hernias since the multiple repair surgeries and mesh implantations.

110. Plaintiff cannot carry out his daily activities without being extremely cautious due to the pain and bulging of his abdomen.

111. As a direct and proximate result of the implanted mesh products into his body, Plaintiff Kenneth Dunham suffered, is suffering, and/or will continue to suffer the abovementioned injuries, including the risk of malfunction, decreased efficacy, recurrent hernia, perforation of tissue and/or organs, adherence to tissue/organs, infection, nerve damage, subsequent surgeries, and other complications.

112. As a direct and proximate result of the wrongful acts and omissions of Defendant, Plaintiff Kenneth Dunham has suffered economic damages, severe and possibly permanent injuries, and emotional distress. Plaintiff has also endured and continues to suffer the mental anguish and psychological trauma of living with these defective products implanted in his body.

COUNT I
STRICT LIABILITY- DEFECTIVE MANUFACTURE

113. Plaintiff incorporates by reference all prior paragraphs of this Complaint as if fully set forth herein.

114. Defendant placed its hernia mesh products, defined herein, into the stream of commerce with the actual or constructive knowledge that it would be used without inspection for defects.

115. Defendant's hernia mesh products were defective in their manufacture.

116. At the time the ProGrip™ Mesh was was implanted into Plaintiff, Defendant's mesh product was defective in its manufacture in that the product deviated from manufacturing standards when they came off the production line.

117. At the time the Parietex™ Mesh was implanted into Plaintiff, Defendant's mesh product was defective in its manufacture in that the product deviated from manufacturing standards when they came off the production line.

118. Defendant's hernia mesh products failed to perform in their intended manner due to a flaw in the manufacturing process, evident by Plaintiffs multiple recurrences and injuries, and which will be established by expert testimony.

119. There was an unreasonable risk that the product would not perform safely and effectively for the purpose for which they were intended, hernia repair.

120. Plaintiff was a reasonably foreseeable user of the product.

121. The ProGrip™ Mesh was implanted into Plaintiff for the purpose of hernia repair; the specified purpose of such product.

122. The Parietex™ Mesh was implanted into Plaintiff for the purpose of hernia repair; the specified purpose of such product.

123. Plaintiff and Plaintiff's physicians, through the exercise of reasonable care, would not have discovered the products defects or perceived its danger.

124. Plaintiff and Plaintiff's physicians, through the exercise of reasonable care, would not have been able to avert Plaintiff's injuries or damages associated with the use of these defective products.

125. As a direct and proximate result of the defective and unreasonably dangerous hernia mesh products, Plaintiff has suffered serious bodily injuries, including constant abdominal pain,

scar tissue, and recurrent hernias that have resulted in pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expenses of hospitalization, medical and nursing care and treatment, and interest on the foregoing injuries.

126. The foregoing losses and injuries are either permanent or continuing and Plaintiff will continue to suffer those losses in the future.

COUNT II
STRICT LIABILITY- DEFECTIVE DESIGN

A. ProGrip™ Mesh

127. Plaintiff incorporates by reference all prior paragraphs of this Complaint as if fully set forth herein.

128. Defendant placed its hernia mesh products, defined herein, into the stream of commerce with the actual or constructive knowledge that it would be used without inspection for defects.

129. At the time the ProGrip™ Mesh was implanted into Plaintiff, Defendant's mesh product was defective in its design.

130. The defects existed when the products were under the control of and distributed by the Defendant.

131. The ProGrip™ Mesh is a lightweight, semi-resorbable mesh designed for tack-free (and suture-free) fixation in the body; it is comprised of a monofilament polyester (PET) material, a collagen film, and a resorbable polylactic acid (PLA) gripping system.

132. Polyester is a synthetic fiber derived from coal, air water, and petroleum.

133. Polyester is used chiefly to make synthetic textile fibers commonly found in clothing, home furnishings, and recording tapes.

134. In the ProGrip™ Mesh, polyester fibers are constructed into a macroporous design which allows the mesh to be stretched in different directions.

135. Collagen is a protein found in connective tissue all throughout the body.

136. These materials, polyester and collagen, respectively, are designed to work in concert to reinforce soft tissue and minimize tissue attachment to the mesh device in case of direct contact with internal organs.

137. However, the collagen film fails to mitigate the body's adverse reaction to the non-absorbable polyester mesh. Polyester is prone to tearing, ripping, and/or fraying.

138. Once the polyester fibers unravel, they become detached from the mesh and migrate to other regions of the body.

139. These polyester fibers, once they become imbedded in different regions of the body, create an inflammatory response.

140. The collagen film which was designed to make the polyester textile more tolerable to the body is extremely delicate.

141. Once the collagen barrier dissolves, internal organs are left unprotected from the dangers associated with the synthetic polyester textile.

142. Once the collagen barrier dissolves, it leaves the internal organs unprotected and increases the chances of adhesions, inflammatory response to the polyester, and formation of devastating scar tissue.

143. Again, as the collagen dissolves there is an increased chance of adhesions and the formation of scar tissue.

144. Further, heavyweight small-pore meshes may withstand greater forces of scar contraction than large-pore lightweight meshes and may exhibit less shrinkage.

145. This is a large pore mesh, prone to contraction and shrinkage.

146. In addition to the polyester fibers unraveling, the mesh can also cause nerve damage.

147. Nerves grow into the macro pores of the polyester textile after implant.

148. Polyester mesh contracts overtime, causing tension to increase where it is secured.

149. The stretching of the nerves causes debilitating pain. Additionally, this pain caused from the stretching of the nerves is essentially unable to be treated.

150. With this in mind, Covidien attached thousands of “micro-grips” to the mesh for a “stronger,” “tension-free” hernia repair.

151. However, micro-grip technology does not prevent the polyester material from contracting and pulling on the tissues and nerves upon which the micro-grips are attached.

152. Several clinical studies indicate self-gripping mesh is not associated with lower rates of chronic and severe post-operative pain or hernia recurrence than is traditional mesh that requires tacks or sutures.

153. Because of defects in the Defendant’s hernia mesh product, it is, and at all times material hereto was, unreasonably dangerous.

154. Alternative designs for hernia mesh product and/or procedures existed that were and/or are less dangerous and equally, if not more, effective, including the use of hemp, polycarbonate and polystyrene as alternatives; as well as a heavyweight small-pore mesh design. Further, a flat mesh and/or non-woven mesh are feasible alternatives that are less dangerous, equally effective and economically feasible.

155. Hemp is a high-yield crop that grows very rapidly and with little irrigation (50% less than cotton), making it a very appealing and “clean” option.

156. Hemp is grown without the use of harmful chemicals, pesticides, herbicides or fertilizers, reducing the body's risk of adverse reaction to the material and reducing the chance of an inflammatory effect. It is also hypoallergenic, which reduces the chance of inflammation and adverse reactions, breathable, and UV resistant.

157. Defendant owed a duty to Plaintiff, Plaintiff's physicians, and others in the medical community and other foreseeable Plaintiff.

158. Defendant breached that duty by marketing a product that was not reasonably safe.

159. The defective design was a proximate cause of Plaintiff's injuries as it did not strengthen the surrounding scar tissue, which lead to multiple recurrences, as well as nerve endings growing pores of the lightweight, macroporous mesh, causing debilitating pain.

160. Even through the exercise of reasonable care, Plaintiff and Plaintiff's physicians could not have discovered the defects and its perceived danger.

161. Plaintiff would not have been able to avert her injury or damages through the exercise of reasonable care.

162. Defendant's hernia mesh product left the Defendant's hands in a condition not reasonably contemplated by the ultimate consumer and unreasonably dangerous for its intended use.

163. At the time of the defects, Defendant's mesh product was being used for the purpose and manner normally intended; specifically, hernia repair.

164. As a direct and proximate result of the defective and unreasonably dangerous hernia mesh product, Plaintiff has suffered serious bodily injuries that have resulted in pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expenses of hospitalization, medical and nursing care and treatment, and interest on the foregoing injuries.

165. The foregoing losses and injuries are either permanent or continuing and Plaintiff will continue to suffer those losses in the future.

B. Parietex™ Mesh

166. Plaintiff incorporates by reference all prior paragraphs of this Complaint as if fully set forth herein.

167. Defendant placed its hernia mesh products, defined herein, into the stream of commerce with the actual or constructive knowledge that it would be used without inspection for defects.

168. At the time the Parietex™ Mesh was implanted into Plaintiff, Defendant's mesh product was defective in its design.

169. The defects existed when the products were under the control of and distributed by the Defendant.

170. The Parietex™ Mesh is a two-sided mesh device made up of a three-dimensional multifilament polyester knit textile on one side and an absorbable collagen film barrier on the other side.

171. Polyester is a synthetic fiber derived from coal, air, water, and petroleum.

172. Polyester is used chiefly to make synthetic textile fibers commonly found in clothing, home furnishings, and recording tapes.

173. In the Parietex™ Optimized Composite Mesh device, polyester fibers are knit into a x-stitch textile; this design creates macro pores (holes) throughout the mesh and allows the mesh to be stretched in different directions.

174. Collagen is a protein found in connective tissue all throughout the body.

175. These materials, polyester and collagen, respectively, are designed to work in concert to reinforce soft tissue and minimize tissue attachment to the mesh device in case of direct contact with internal organs.

176. However, the collagen film fails to mitigate the body's adverse reaction to the non-absorbable polyester mesh.

177. Once the collagen barrier dissolves, it leaves the internal organs unprotected and increases the chances of adhesions, inflammatory response to the polyester, and formation of devastating scar tissue.

178. Again, as the collagen dissolves there is an increased chance of adhesions and the formation of scar tissue.

179. Further, heavyweight small-pore meshes may withstand greater forces of scar contraction than large-pore lightweight meshes and may exhibit less shrinkage.

180. This is a large pore mesh, prone to contraction and shrinkage.

181. Polyester is prone to tearing, ripping, and/or fraying.

182. Once the polyester fibers unravel, they become detached from the mesh and migrate to other regions of the body.

183. These Polyester fibers, once they become imbedded in different regions of the body, create an inflammatory response.

184. In addition to unraveling of the polyester fibers, the mesh can also cause nerve damage.

185. Nerves can grow into the pores of the x-stitch textile after implant.

186. Polyester mesh contracts overtime, causing tension to increase where it is secured by tacks or sutures.; or in this case, micro-grips.

187. The nerves stretching causes debilitating pain.

188. Additionally, pain caused from nerves stretching is essentially unable to be treated.

189. Multifilament polyester hernia mesh product are associated with higher rates of medical complications per patient, including but not limited to: infection, small bowel obstruction, fistula formation, and hernia recurrence.

190. As a result, several clinical studies have recommended against the use of macro-porous polyester mesh for incisional hernia repair.

191. The collagen film designed to make the polyester textile more tolerable to the body is extremely delicate.

192. Once the collagen barrier dissolves, internal organs are left unprotected from the dangers associated with the synthetic polyester textile.

193. Because of defects in the Defendant's hernia mesh product, it is, and at all times material hereto was, unreasonably dangerous.

194. Alternative designs for hernia mesh product and/or procedures existed that were and/or are less dangerous and equally, it not more, effective, including the use of hemp, polycarbonate and polystyrene as alternatives; as well as a heavyweight small-pore mesh design. Further, a flat mesh and/or non-woven mesh are feasible alternatives that are less dangerous, equally effective and economically feasible.

195. Hemp is a high-yield crop that grows very rapidly and with little irrigation (50% less than cotton), making it a very appealing and "clean" option.

196. Hemp is grown without the use of harmful chemicals, pesticides, herbicides or fertilizers, reducing the body's risk of adverse reaction to the material and reducing the chance of

an inflammatory effect. It is also hypoallergenic, which reduces the chance of inflammation and adverse reactions, breathable, and UV resistant.

197. Defendant owed a duty to Plaintiff, Plaintiff's physicians, and others in the medical community and other foreseeable Plaintiff.

198. Defendant breached that duty by marketing a product that was not reasonably safe.

199. The defective design was a proximate cause of Plaintiff's injuries as it did not strengthen the surrounding scar tissue, which lead to multiple recurrences, as well as nerve endings growing pores of the lightweight, macroporous mesh, causing debilitating pain.

200. Even through the exercise of reasonable care, Plaintiff and Plaintiff's physicians could not have discovered the defects and its perceived danger.

201. Plaintiff would not have been able to avert her injury or damages through the exercise of reasonable care.

202. Defendant's hernia mesh product left the Defendant's hands in a condition not reasonably contemplated by the ultimate consumer and unreasonably dangerous for its intended use.

203. At the time of the defects, Defendant's mesh product was being used for the purpose and manner normally intended; specifically, hernia repair.

204. As a direct and proximate result of the defective and unreasonably dangerous hernia mesh product, Plaintiff has suffered serious bodily injuries that have resulted in pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expenses of hospitalization, medical and nursing care and treatment, and interest on the foregoing injuries.

205. The foregoing losses and injuries are either permanent or continuing and Plaintiff will continue to suffer those losses in the future.

206. Because of defects in the Defendant's hernia mesh product, it is, and at all times material hereto was, unreasonably dangerous.

207. Defendant breached that duty by marketing a product that was not reasonably safe.

208. The defective design was a proximate cause of Plaintiff's injuries as it did not strengthen the surrounding scar tissue, which lead to multiple recurrences, as well as nerve endings growing pores of the lightweight, macroporous mesh, causing debilitating pain.

209. Even through the exercise of reasonable care, Plaintiff and Plaintiff's physicians could not have discovered the defects and its perceived danger.

210. Plaintiff would not have been able to avert her injury or damages through the exercise of reasonable care.

211. Defendant's hernia mesh product left the Defendant's hands in a condition not reasonably contemplated by the ultimate consumer and unreasonably dangerous for its intended use.

212. At the time of the defects, Defendant's mesh product was being used for the purpose and manner normally intended; specifically, hernia repair.

213. As a direct and proximate result of the defective and unreasonably dangerous hernia mesh product, Plaintiff has suffered serious bodily injuries, including constant abdominal pain, scar tissue, and recurrent hernias that have resulted in pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expenses of hospitalization, medical and nursing care and treatment, and interest on the foregoing injuries.

214. The foregoing losses and injuries are either permanent or continuing and Plaintiff will continue to suffer those losses in the future.

COUNT III.
STRICT LIABILITY- FAILURE TO WARN

215. Plaintiff incorporate by reference all prior paragraphs of this Complaint as if fully set forth herein.

A. ProGrip™ Mesh

216. The ProGrip™ Mesh implanted in Plaintiff was defective and unreasonably dangerous when it left the possession of the Defendant in that it contained warnings which were inadequate and insufficient to alert physicians or consumers to the dangerous risks associated with the product, including, without limitation, extreme pain, risk of malfunction, decreased efficacy, recurrent hernia, perforation of tissue and/or organs, adherence to tissue/organs, infection, nerve damage, subsequent surgeries and other complications.

217. Defendant's website located at <https://www.medtronic.com/covidien/en-us/products/hernia-repair/progrip-laparoscopic-self-fixating-mesh.html> does not reference any information about warnings and adverse effects.

218. The ProGrip™ Mesh implanted in Plaintiff was defective and unreasonably dangerous when it left the possession of the Defendant in that the Defendant failed to include proper directions for use, implantation, and/or removal.

219. Specifically, Defendant completely failed to warn about the fact that as the collagen erodes, it increases the likelihood of adhesion formation, the formation of debilitating scar tissue, and the bodies likelihood of an inflammatory response to the polyester material.

220. Defendant failed to warn about the high likelihood of mesh shrinkage, contraction, and migration, which are side effects of the large-pore meshes such as this one.

221. Defendant failed to warn about persistent peritoneal bacteraemia that can form from the implanting of the mesh, as well as the mesh fraying, unraveling and tearing.

222. Defendant's ProGrip™ Mesh implanted in Plaintiff was used for its intended purpose, i.e., repair hernias through reinforcement.

223. Plaintiff's physicians, including the surgeons who performed the implants of the Defendant's ProGrip™ Mesh, could not have discovered any defect with the product through the exercise of care.

224. Plaintiff's physicians, including the surgeon who performed the implant of Defendant's ProGrip™ Mesh, did not have substantially the same knowledge that an adequate warning from the manufacturer or a distributor would have communicated.

225. The warnings that were provided by Defendant regarding its ProGrip™ Mesh were ambiguous or were not sufficient, accurate or clear.

226. The Defendant had a continuing duty to warn Plaintiff and his doctors of the dangers associated with its ProGrip™ Mesh.

227. As a direct and legal result of the Defendant's failure to warn, Plaintiff has suffered serious bodily injuries, resulting in pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expenses of hospitalization, medical and nursing care and treatment, and interest on the foregoing. The foregoing losses and injuries are either permanent or continuing and Plaintiff will suffer the losses in the future.

228. Plaintiff's physicians would not have elected to use Defendant's ProGrip Mesh had it been equipped with sufficient warnings, including the possibility for mesh migration, failure, and the need for future surgeries.

229. As a direct and legal result of the Defendant's failure to warn, Plaintiff has suffered serious bodily injuries, including constant abdominal pain, scar tissue, and recurrent hernias resulting in pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of

life, expenses of hospitalization, medical and nursing care and treatment, and interest on the foregoing. The foregoing losses and injuries are either permanent or continuing and Plaintiff will suffer the losses in the future.

B. Parietex™ Mesh

230. The Parietex™ Mesh implanted in Plaintiff was defective and unreasonably dangerous when it left the possession of the Defendant in that it contained warnings which were inadequate and insufficient to alert physicians or consumers to the dangerous risks associated with the product, including, without limitation, extreme pain, risk of malfunction, decreased efficacy, recurrent hernia, perforation of tissue and/or organs, adherence to tissue/organs, infection, nerve damage, subsequent surgeries and other complications.

231. Defendant's brochure for the Parietex™ Mesh located at <http://www.medtronic.com/content/dam/covidien/library/us/en/product/hernia-repair/parietex-optimized-composite-and-pcox-mesh-absorbatack-fixation-device-brochure.pdf> has a very minimal amount of information for the general public regarding warnings and adverse effects.

232. Defendants Parietex™ Mesh implanted in Plaintiff was defective and unreasonably dangerous when it left the possession of the Defendant in that the Defendant failed to include proper directions for use, implantation, and/or removal.

233. Specifically, Defendant completely failed to warn about the fact that as the collagen erodes, it increases the likelihood of adhesion formation, the formation of debilitating scar tissue, and the bodies likelihood of an inflammatory response to the polyester material.

234. Defendant failed to warn about the high likelihood of mesh shrinkage, contraction, and migration, which are side effects of the large-pore meshes such as this one.

235. Defendant failed to warn about persistent peritoneal bacteraemia that can form from the implanting of the mesh, as well as the mesh fraying, unraveling and tearing.

236. Further, defendant failed to warn about the fact that the micro-grips or Velcro like hooks make it much more difficult to remove the mesh once implanted.

237. Defendant's Parietex™ Mesh implanted in micrPlaintiff was used for its intended purpose, i.e., repair hernias through reinforcement.

238. Plaintiff's physicians, including the surgeons who performed the implants of the Defendant's Parietex™ Mesh, could not have discovered any defect with the product through the exercise of care.

239. Plaintiff's physicians, including the surgeon who performed the implant of Defendant's hernia mesh product, did not have substantially the same knowledge that an adequate warning from the manufacturer or a distributor would have communicated.

240. The warnings that were provided by Defendant regarding its Parietex™ mesh were ambiguous or were not sufficient, accurate or clear.

241. The Defendant had a continuing duty to warn Plaintiff and his doctors of the dangers associated with its hernia mesh product.

242. Plaintiff's physicians would not have elected to use Defendant's Parietex™ Mesh had it been equipped with sufficient warnings, including the possibility for mesh migration, failure, chronic pain, and the need for future surgeries.

243. As a direct and legal result of the Defendant's failure to warn, Plaintiff has suffered serious bodily injuries, including constant abdominal pain, scar tissue, and recurrent hernias, resulting in pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expenses of hospitalization, medical and nursing care and treatment, and interest on the foregoing. The foregoing losses and injuries are either permanent or continuing and Plaintiff will suffer the losses in the future.

COUNT IV
NEGLIGENCE

244. Plaintiff incorporates by reference all prior paragraphs of this Complaint as if fully set forth herein.

245. Defendant owed a duty to Plaintiff, and others similarly situated as foreseeable users of its hernia mesh product, to research, design, develop, test, manufacture, inspect, and sell its products in a reasonably safe manner for its intended use, free from defects.

246. Defendant owed a duty of care to Plaintiff to adequately warn against the risks associated with the foreseeable uses of the hernia mesh products which the Defendant knew or should have known.

247. Defendants breached this duty through its failure to adequately warn of the following risks, which they knew or should have known:

- a. the potential for perforation into human tissue;
- b. the potential to erode or “break down”;
- c. the potential to decrease in efficacy;
- d. the potential to cause patients observable abdominal bulging and pain many months after implantation;
- e. the potential for excessive scar tissue formation due to hernia mesh implantation, requiring future excision of scar tissue and lysis of adhesions;
- f. the potential for its hernia mesh product to overlie human tissue;
- g. muscle loss, weight gain, and/or continuous stomach pain associated with and/or caused by its hernia mesh product;
- h. loss of bowel function; increased diarrhea and stool related issues; loss in mobility; and
- i. death.

248. Defendants breached their duty through the failure to properly research and design the mesh product to prevent or mitigate these risks through the use of materials such as hemp, polystyrene, or polycarbonate.

249. Defendants breached their duty through the failure to properly research and design the mesh product through its failure to use a non-woven or flat mesh to eliminate pores which nerves can grow into.

250. Defendant was negligent in designing, manufacturing, and selling the hernia mesh products by, among other things, failing to properly fabricate the hernia mesh product, failing to adequately test the hernia mesh product, and failing to conduct adequate quality control procedures for the hernia mesh product.

251. Defendant breached its duty by failing to adequately warn Plaintiff and/or his physicians and/or the medical community of, inter alia, the aforementioned risks associated with the hernia mesh products, and that failure directly caused Plaintiff's injuries.

252. The defective design of the Defendants mesh product caused the Plaintiff's injuries as it did not strengthen the surrounding scar tissue, which lead to multiple recurrences, as well as nerve endings growing pores of the lightweight, macroporous mesh, causing debilitating pain.

253. The Defendant's failure to adequately warn Plaintiff and/or his physicians and/or the medical community of these risks lead to the Plaintiff being implanted with this mesh, which has failed, causing him to suffer constant pain, scar tissue and recurrent hernias, which were not properly warned of.

254. As a direct and proximate result of the Defendant's defective and unreasonably dangerous hernia mesh product, Plaintiff has suffered serious bodily injuries, including constant abdominal pain, scar tissue, and recurrent hernias that have resulted in pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expenses of hospitalization, medical and nursing care and treatment, and interest on the foregoing.

255. The foregoing losses and injuries are either permanent or continuing and Plaintiff will suffer the losses in the future.

COUNT V
BREACH OF EXPRESS WARRANTY

256. Plaintiff incorporates by reference all prior paragraphs of this Complaint as if fully set forth herein.

257. Defendant expressly warranted to Plaintiff and Plaintiff's physicians that its product was safe and effective for the use of hernia repair.

258. Specifically, Defendant expressly warranted that its product, the ProGrip™ Mesh, "eliminates the pain associated with traditional tax fixation," "low post-operative pain and fast recovery in laparoscopic inguinal hernia repairs," "easy to use."

259. These warranties were in fact, false.

260. Specifically, the mesh did not eliminate the pain of fixation, or the post-operative pain.

261. Plaintiff still has pain in the abdomen around or near the site of the implant caused by the micro-grips used on the mesh to secure it and/or nerve endings growing into the woven pores of the mesh.

262. Defendant expressly warranted that its product, the Parietex™ Mesh, was "the most complete hernia repair solution" and one of "the most studied, innovative and reliable hernia products available today."

263. Defendant's hernia mesh products were defective in their manufacture and design and were therefore, not fit for their intended use.

264. Specifically, the mesh was not reliable, nor was it a hernia repair solution as the Plaintiff has had recurring hernias, constant pain and scar tissue since the mesh was implanted.

265. Defendant's hernia mesh products were defective in their manufacture and design and was therefore, not designed, manufactured, or sold in accordance with good design, engineering, and industry standards.

266. Plaintiff and Plaintiff's physician relied on these warranties when making the determination to use Defendant's products for Plaintiff's hernia repair surgeries.

267. Defendant breached the above warranties in that its hernia mesh products were defective as set forth above, was not fit for their intended use and were not designed, manufactured, or sold in accordance with good design, engineering and industry standards.

268. As a direct and proximate result of Defendant's defective and unreasonably dangerous hernia mesh products, Plaintiff has suffered serious bodily injuries, including constant abdominal pain, scar tissue, and recurrent hernias, that have resulted in pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expenses of hospitalization, medical and nursing care and treatment, and interest on the foregoing. The foregoing losses and injuries are either permanent or continuing and Plaintiff will suffer the losses in the future.

COUNT VI
BREACH OF IMPLIED WARRANTY

269. Defendant impliedly warranted to Plaintiff and all others similarly situated that its hernia mesh products were reasonably fit for its ordinary and intended use and that they were designed, manufactured, and sold in accordance with good design, engineering, and industry standards.

270. Defendant promoted and marketed its products for the purpose of hernia repair.

271. Defendant impliedly warranted that its products were safe and effective for both its ordinary and particular purpose of surgical repair, and specifically, hernia repair.

272. Plaintiff's physicians opted to implant Defendant's products into Plaintiff for its intended purpose; specifically, hernia repair.

273. Plaintiff and Plaintiff's physician relied on these warranties, and Defendant's expertise, when making the determination to use Defendant's products for Plaintiff's hernia repair surgery.

274. Defendant breached the above warranties in that its hernia mesh products were defective as set forth above, were not fit for their intended use and were not designed, manufactured, or sold in accordance with good design, engineering and industry standards.

275. As a direct and proximate result of Defendant's hernia mesh products, which were not suitable for its purpose, Plaintiff has suffered serious bodily injuries, including constant abdominal pain, scar tissue, and recurrent hernias that have resulted in pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expenses of hospitalization, medical and nursing care and treatment, and interest on the foregoing. The foregoing losses and injuries are either permanent or continuing and Plaintiff will suffer the losses in the future.

COUNT VII
NEGLIGENT MISREPRESENTATION

276. Plaintiff incorporates by reference all prior paragraphs of this Complaint as if fully set forth herein.

277. Defendant had a duty to represent truthfully and accurately to the medical community, the FDA, and United States consumers accurately and truthfully, including Plaintiff, the results of Defendant's hernia mesh products testing. The misrepresentations made by Defendant were false; Defendant was careless or negligent in ascertaining the truth of the representations at the time Defendant made the misrepresentations.

278. Defendant represented and marketed its hernia mesh products as being safe and effective.

279. Defendant materially misrepresented to the medical community, potential plaintiffs and Plaintiff alike, the effectiveness of the mesh without representing the potential for failure, bacteria, adhesions, contraction and shrinkage.

280. Defendant made material misrepresentations as to the amount of pain those implanted with the meshes would feel.

281. Defendant specifically warranted and represented that those implanted with the Parietex™ / Progrip™ meshes that there would be less post operative pain, as well as less pain from fixation. Defendant never represented the fact that there are “micro-grips” or Velcro-like hooks used to alleviate the need of tacks or sutures to secure the polyester mesh. However, these are equivalent to tacks and cause just as much pain and make it more difficult to remove the mesh.

282. After Defendant became aware of the risks of its hernia mesh products, Defendant failed to accurately communicate those risks associated with its products.

283. Defendant failed to exercise ordinary care in the representation concerning its product and its manufacture, sale, testing, quality assurance, quality control, and distribution. Defendant negligently and/or carelessly misrepresented and intentionally concealed the truth regarding the high risk of the product’s unreasonable, dangerous, and adverse side effects associated with the administration, use, and implantation of the products.

284. Defendant breached its duty in representing to Plaintiff, her physicians, and health care providers, and the medical community, that its hernia mesh product did not carry the risk of serious side effects such as those suffered by Plaintiff and other similarly situated patients.

285. Plaintiff, Plaintiff's health care providers, physicians, and surgeons justifiably relied on Defendant's negligent misrepresentations.

286. As a direct and proximate consequence of Defendant's negligent misrepresentations, Plaintiff has sustained serious personal injuries, including constant abdominal pain, scar tissue, and recurrent hernias, mental anguish, physical pain and suffering, diminished capacity for the enjoyment of life, a diminished quality of life, medical and related expenses, and other losses and damages.

COUNT VIII
FRAUDULENT MISREPRESENTATION

287. Plaintiff incorporates by reference all prior paragraphs of his Complaint as if fully set forth herein.

288. Defendant made misrepresentations of material fact from 2014 to present to Plaintiff and his physicians, to induce them to use the ProGrip™ Mesh for hernia repair, including:

- a. Covidien's webpage pertaining to the ProGrip™ Mesh, located at; <https://www.medtronic.com/covidien/en-us/products/hernia-repair/progrip-laparoscopic-self-fixating-mesh.html>
- b. The website explicitly warrants Defendant's device as Leading the future of fixation, self fixating, less pain, easy to use and lower costs.

289. Defendant made misrepresentations of material fact from 2011 to present to Plaintiff and his physicians, to induce them to use the Parietex™ Mesh for hernia repair, including:

- a. Covidien's webpage pertaining to the Parietex™ mesh, located at <https://www.medtronic.com/covidien/en->

[us/products/hernia-repair/mesh-products.html#parietex-composite-hiatal-pco-2h-mesh](https://www.parietex.com/us/products/hernia-repair/mesh-products.html#parietex-composite-hiatal-pco-2h-mesh).

b. The website explicitly warrants Defendant's device as "materials are designed for optimal abdominal wall conformability. "Provides easy deployment and fixation system. Supports tissue integration while minimizing visceral attachment with collagen film."

290. Defendants made false and misleading representations of the risks of the both the ProGrip™ Mesh and the Parietex™ Mesh in literature distributed to the medical community.

291. Defendants misrepresented material information regarding the ProGrip™ Mesh and the Parietex™ Mesh by failing to disclose the known risks of their Hernia Mesh products and predecessor devices.

292. Defendants intentionally, willfully, knowingly, and fraudulently misrepresented to the medical community, the FDA, and consumers, including the Plaintiff Kenneth Dunham and his health care providers, that their hernia mesh products had been adequately tested in clinical trials and were found to be safe and effective.

293. The information distributed by Defendant to the public, including the Plaintiffs, the medical community, and the FDA, included, but was not limited to, reports, press releases, advertising campaigns, print advertisements, commercial media containing material representations, which were false and misleading, and contained omissions and concealment of the truth regarding the dangers of the use of Defendant's hernia mesh products.

294. Product brochures are commonly used by medical device manufacturers and designers, such as Defendant's, as advertisement material, and can be used by sellers such as

Defendant's to communicate terms of warranty to a buyer and can be a presumptive part of the agreement.

295. Defendant used its product brochures to communicate terms of warranty and representations about their products to their buyers, including but not limited to Plaintiff Kenneth Dunham's physicians and/or medical providers.

296. Defendant's products brochures do not provide detail about the potential complications associated with their products.

297. Plaintiffs health care providers and medical facilities relied on the misrepresentations by Defendant in the product brochures and websites for each mesh.

298. Defendant made continuous misrepresentations regarding the safety and efficiency of their products to Plaintiff Kenneth Dunham's medical providers and medical facilities through "Dear Doctor" letters, and "Medical Information Letters," and when leaving the following materials for doctors: promotional materials, folders with clinical studies in Defendants' favor, and product samples. Defendant also made such misrepresentations when hosting dinner events during which they promoted their products, continuing medical education events where they promoted their products, lectures where they promoted their products, and happy hours where they promoted their products. These promotional events occurred from 2011 and 2014, respectively, to the present.

299. Defendant, as designer and manufacturer of pharmaceutical implant devices, with ample resources and sophistication, had actual knowledge of all risks of both the ProGrip™ Mesh and the Parietex™ Mesh.

300. Defendant engaged in commercial conduct by selling both the ProGrip™ Mesh and the Parietex™ Mesh.

301. Defendant knew at the time it made their misrepresentations and omissions that they were false.

302. Defendant intended that Plaintiffs would rely on their misrepresentations and omissions.

303. Given Defendants ample resources and sophistication as designers and manufacturers of pharmaceutical implant devices, Plaintiff Kenneth Dunham, through his physicians and healthcare providers, and his physicians reasonably relied upon Defendant's misrepresentations and omissions regarding the safety and efficacy of Defendant's hernia mesh products, resulting in Plaintiffs sustaining permanent personal injuries and damages.

304. In reliance upon Defendant's false and fraudulent misrepresentations, through his physicians and healthcare providers, the Plaintiff was induced to, and did, reasonably rely upon Defendant's misrepresentations and omissions regarding the safety and efficacy of Defendant's hernia mesh products, resulting in Plaintiffs sustaining permanent personal injuries and damages.

305. Defendant had sole access to material facts concerning the defective nature of its hernia mesh products and its propensity to cause serious and dangerous injuries and damages to persons who used their hernia mesh products.

306. Defendant had sole access to material facts concerning the defective nature of the products and their propensities to cause serious and dangerous side effects in the form of dangerous injuries and damages to persons who are implanted with the ProgridTM Mesh and the ParietexTM Mesh.

307. Defendant knew, and had reason to know, that their hernia mesh products could cause serious personal injury to those who received an implant, and that their hernia mesh product

were inherently dangerous in a manner that exceeded the inaccurate and inadequate warnings given.

308. Defendant made fraudulent misrepresentations and omissions intentionally, willfully, wantonly, and with reckless disregard and depraved indifference for the safety and well-being of the users of their products, including Plaintiffs.

309. Defendant's wrongful conduct was fraudulent, deceitful, committed and perpetrated willfully, wantonly, and purposefully.

310. Defendant's fraudulent misrepresentations and omissions were made with the intent of defrauding and deceiving the medical community and the public, including Plaintiffs, and to induce the medical community to recommend, dispense and purchase Defendant's hernia mesh products.

311. As a foreseeable, direct, and proximate result of Defendant's described misrepresentations and omissions, Plaintiffs suffered the serious and dangerous side effects more specifically described in this Complaint.

312. As a direct and proximate consequence of Defendant's fraudulent misrepresentations, Plaintiffs sustained serious personal injuries, including constant abdominal pain, scar tissue, and recurrent hernias, and related losses including mental anguish, physical pain and suffering, diminished capacity for the enjoyment of life, a diminished quality of life, diminished ability to work, medical and related expenses, and other losses and damages.

COUNT IX
NEGLIGENT MISREPRESENTATION

313. Plaintiffs incorporate by reference all prior paragraphs of this Complaint as if fully set forth herein.

314. Defendant had a duty to represent truthfully and accurately to the medical community, the FDA, and United States consumers accurately and truthfully, including Plaintiffs, the results of Defendants' hernia mesh products testing. The misrepresentations made by Defendants were false; Defendants were careless or negligent in ascertaining the truth of the representations at the time Defendants made the misrepresentations.

315. Defendant represented and marketed their hernia mesh products as being safe and effective.

316. After Defendant became aware of the risks of their hernia mesh products, Defendant failed to accurately communicate those risks associated with its products.

317. Defendant failed to exercise ordinary care in the representation concerning its products and their manufacture, sale, testing, quality assurance, quality control, and distribution. Defendant negligently and/or carelessly misrepresented and intentionally concealed the truth regarding the high risk of the products' unreasonable, dangerous, and adverse side effects associated with the administration, use, and implantation of the products.

318. Defendant breached its duty in representing to Plaintiff Kenneth Dunham, his physicians and healthcare providers, and the medical community, that its hernia mesh products did not carry the risk of serious side effects such as those suffered by Plaintiff and other similarly situated patients.

319. Plaintiff Kenneth Dunham, and his healthcare providers, physicians, and surgeons justifiably relied on Defendants negligent misrepresentations.

320. As a direct and proximate consequence of Defendant's negligent misrepresentations, Plaintiffs have sustained serious personal injuries, including constant abdominal pain, scar tissue, and recurrent hernias, mental anguish, physical pain and suffering,

diminished capacity for the enjoyment of life, a diminished quality of life, medical and related expenses, and other losses and damages.

COUNT X
UNJUST ENRICHMENT

321. Plaintiff incorporates by reference all prior paragraphs of this Complaint as if fully set forth herein.

322. Defendant is, and at all times was, the manufacturers, sellers, suppliers, distributors, marketers, and/or dealers of the Progrip™ Mesh and the Parietex™ Mesh.

323. Plaintiff paid for Defendant's hernia mesh products for the purpose of hernia repair.

324. Defendant has accepted payment by Plaintiffs for the purchase of their hernia mesh products.

325. Plaintiffs has not received the safe and effective hernia mesh products for the hernia repair material for which they paid.

COUNT XI
CONSUMER FRAUD - VIOLATION OF GBL §349 and §350

326. Plaintiff incorporates by reference all prior paragraphs of this Complaint as if fully set forth herein.

327. The Defendant acted, used and employed unconscionable commercial practices, deception, fraud, false pretenses, false promises and misrepresentations, and knowingly concealed, suppressed and omitted material facts with the intent that consumers, including Plaintiff herein and Plaintiff Kenneth Dunham's physicians and medical providers, rely upon such concealment, suppression and omission, in connection with sale, advertisement and promotion of their hernia mesh products (the Progrip™ Mesh and the Parietex™ Mesh), in violation of all applicable state consumer fraud statutes, for the purpose of influencing and inducing physicians and medical providers to implant the Defendants' hernia mesh products the Progrip™ Mesh and the Parietex™

Mesh) to patients/consumers such as the Plaintiffs herein. Because of the Defendant's unconscionable, deceptive and fraudulent acts and practices, and false pretenses, false promises and misrepresentations, reasonable patients/consumers acting reasonably, such as the Plaintiffs herein, were caused to suffer ascertainable loss of money and property and actual damages.

328. Defendant engaged in consumer-oriented, commercial conduct by selling and advertising the subject products.

329. Defendant misrepresented and omitted material information regarding the subject products by failing to disclose known risks.

330. Defendant's misrepresentations and concealment of material facts constitute unconscionable commercial practices, deception, fraud, false pretenses, misrepresentation, and/or the knowing concealment, suppression, or omission of materials facts with the intent that others rely on such concealment, suppression, or omission in connection with the sale and advertisement of the subject product, in violation of New York General Business Law ("GBL") §§ 349 and 350.

331. New York has enacted statutes to protect consumers from deceptive, fraudulent and unconscionable trade and business practices. Defendant violated these statutes by knowingly and falsely representing that the subject products were fit to be used for the purpose for which it was intended, when the Defendants knew said products were defective and dangerous, and by other acts alleged herein.

332. Defendant engaged in the deceptive acts and practices alleged herein in order to sell the subject products to the public, including Plaintiffs.

333. Specifically, Defendant completely failed to warn about the fact that as the collagen erodes, it increases the likelihood of adhesion formation, the formation of debilitating scar tissue, and the bodies likelihood of an inflammatory response to the polyester material.

334. Defendant failed to warn about the high likelihood of mesh shrinkage, contraction, and migration, which are side effects of the large-pore meshes such as this one.

335. Defendant failed to warn about persistent peritoneal bacteraemia that can form from the implanting of the mesh, as well as the mesh fraying, unraveling and tearing.

336. As a direct and proximate result of the Defendant's violations of GBL §349 and §350, Plaintiff suffered damages, for which Plaintiff is entitled to compensatory damages, equitable and declaratory relief, punitive damages, costs and reasonable attorneys' fees.

337. As a direct and proximate result of Defendant's conduct, the Plaintiff used and/or had the hernia mesh products at issue (the Progrid™ and the Parietex™ Mesh) and Plaintiff suffered serious physical injury, harm, and damages.

338. Defendant's actions and omissions as alleged in this Complaint demonstrate a flagrant disregard for human life, so as to warrant the imposition of punitive damages.

339. This action falls within one or more of the exceptions set forth in CPLR 1602, and as such the Defendant is liable pursuant to the exceptions set forth in Article 16 of the C.P.L.R.

340. Pursuant to C.P.L.R. Section 1602(2)(iv), Defendant is jointly and severally liable for all of Plaintiffs damages, including but not limited to, Plaintiffs non-economic loss, irrespective of the provisions of C.P.L.R. Section 1601, by reason of the fact that Defendants owed Plaintiffs a non-delegable duty of care.

341. Pursuant to C.P.L.R. Section 1602(2)(iv), Defendant is liable for all of Plaintiffs damages, including but not limited to, Plaintiffs non-economic loss, irrespective of the provisions of C.P.L.R. Section 1601, by reason of the fact that said Defendant is vicariously liable for the negligent acts and omissions of its servants, agents, affiliated physicians, surgeons and/or employees.

342. Pursuant to C.P.L.R. Section 1602(7), Defendant is jointly and severally liable for all of Plaintiffs damages, including but not limited to Plaintiffs non-economic loss, irrespective of the provisions of C.P.L.R. Section 1601, by reason of the fact that said Defendants acted with reckless disregard for the safety of others.

343. By reason of the foregoing, Plaintiff has been damaged in an amount that exceeds the jurisdictional limits of all lower courts, which would otherwise have jurisdiction in this matter.

CLAIM XII
LOSS OF CONSORTIUM
(Plaintiff MARTHA DUNHAM, against DEFENDANTS)

344. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiffs plead this Count in the broadest sense, pursuant to all laws that may apply pursuant to the choice of law principles, including the law of the Plaintiffs' resident State.

345. At all relevant times hereto, where applicable, Plaintiff Kenneth Dunham was married to Plaintiff Martha Dunham, and they continue to be married.

346. Spouse Plaintiffs, Family Member Plaintiffs, and/or intimate partners of the aforesaid Plaintiffs, such as Plaintiff Martha Dunham, has suffered injuries and losses as a result of the Plaintiff Kenneth Dunham injuries from the implantation of Defendant's the Progrid™ Mesh and the Parietex Mesh.

347. For the reasons set forth herein, Plaintiff Martha Dunham has necessarily paid and have become liable to pay for medical aid, treatment, monitoring, medications, and other expenditures and will necessarily incur further expenses of a similar nature in the future as a proximate result of Defendants' misconduct.

348. For the reasons set forth herein, Plaintiff Martha Dunham suffered and will continue to suffer the loss of their loved one's support, companionship, services, society, love and affection.

349. Plaintiffs allege that their marital relationship was impaired and depreciated, and the marital association between husband and wife has been altered.

350. Plaintiffs have suffered great emotional pain and mental anguish.

351. As a direct and proximate result of Defendant's wrongful conduct, Spouse Plaintiffs, Family Member Plaintiffs, and/or intimate partners of the aforesaid Plaintiffs, have sustained and will continue to sustain severe physical injuries, severe emotional distress, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

352. Defendant is liable to Spouse Plaintiffs, Family Member Plaintiffs, and intimate partners jointly and severally for all general, special and equitable relief to which Spouse Plaintiffs, Family Member Plaintiffs, and intimate partners are entitled by law.

WHEREFORE, Plaintiffs demand judgment against the Defendants herein in an amount that exceeds the jurisdictional limitations of all lower courts that would otherwise have jurisdiction over this action, together with the interest, costs and disbursements of same allowed by law.

Dated: New York, New York
July 3, 2019

MARC J. BERN & PARTNERS LLP
Attorneys for Plaintiffs



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